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A stroke preparedness RCT in a multi-ethnic cohort: Design and methods

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ABSTRACT

Background: Tissue plasminogen activator (tPA), the only approved treatment for acute ischemic stroke (IS), is significantly underutilized likely due to poor lay information about stroke as an emergency. In order to improve outcomes in acute IS, it is critical to raise awareness and recognition of stroke symptoms particularly among minority populations. This manuscript describes the application of a stroke preparedness behavioral intervention and includes baseline information in a multi-ethnic population of stroke and transient ischemic attack (TIA) survivors.

Methods: In the Stroke Warning Information and Faster Treatment Study (SWIFT), we prospectively identified, and randomized IS and TIA patients to determine efficacy of a culturally tailored interactive stroke preparedness strategy. Data collected at baseline included acute stroke parameters, stroke knowledge, severity, social resources and vascular risk assessment.

Results: Of the 736 enrolled to date, 76% were IS and 24% TIA events. The cohort was 51% female: 45% Hispanic, 26% White and 25% Black. Over 75% reported hypertension, 36% diabetes, and 16% cardiac disease. Mean time from onset to emergency department (ED) arrival was 46 h (median 13 h) differing significantly between Whites (mean 52 h, median 11 h) and Blacks (mean 52 h, median 17 h) versus Hispanics (mean 39 h, median 11 h). Knowledge that a stroke occurs in the brain differed significantly by between Whites (85%), Blacks (64%), Hispanics (66%, $p<0.000$).

Conclusions: Disparities remain in both action and knowledge surrounding acute stroke. Use of written information has not proven an effective means of changing health behaviors. We propose an interactive culturally tailored intervention to address behavioral change in acute stroke.

1. Introduction

Over 700,000 strokes occur in the US each year with differentials in morbidity and mortality by race-ethnicity. The rapid diagnosis and treatment of acute ischemic stroke are critical in the reduction of morbidity, disability and stroke-associated mortality. While tPA is the only approved treatment for acute IS, less than 2–3% of acute stroke patients actually receive treatment and differentials by race-ethnicity suggested [1–3]. The inability to capture acute IS cases within 3 h of symptom onset is one critical factor. Under-education about stroke may prevent people from recognizing symptoms early enough to seek immediate care. Traditional informational pamphlets along with public ad campaigns demonstrate suboptimal success possibility due to inadequate attention to

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health literacy, or cultural tailoring. Intervention strategies that move away from the didactic approach and utilize health promotion theory to develop intensive, interactive and culturally sensitive programs may not only increase stroke awareness, they may increase the individuals' likelihood to respond more quickly and benefit from life saving stroke therapy. A novel strategy for acute IS would involve an experiential approach to facilitate the rapid identification of stroke symptoms, and urgency to obtain emergency medical treatment.

2. Aims

The following aims guided this trial:

1. To compare the prevalence of early time to arrival ($\leq$2 h) after stroke in the SWIFT intervention group (an interactive culturally tailored 2 *session* stroke educational strategy) versus usual care group among stroke/TIA survivors.
2. To evaluate knowledge efficacy of the SWIFT intervention versus standard care by comparing 30 day and 1 year stroke knowledge among stroke/TIA survivors.

The primary objective of the SWIFT study is to determine whether a culturally tailored, interactive educational program in a racially and ethnically diverse high risk population, aimed at stroke awareness and emergency treatment will lead to increased stroke knowledge, behavioral change and improved time to arrival to the ED upon onset of stroke symptoms. Our first aim reflects our focus on behavioral change and compares the prevalence of early time to arrival ($\leq$2 h) after stroke in the intervention group versus usual care among stroke/TIA survivors. Our second aim examines knowledge as the mediator for behavioral change. In this aim we evaluate the efficacy of the SWIFT intervention versus standard care (educational handouts) in a comparison of 30 day and 1 year stroke knowledge retention among stroke/TIA survivors. In this manuscript we describe the SWIFT intervention methodology and provide information on differences in acute stroke demographics in a multi-ethnic acute stroke/TIA cohort.

3. Methods and design

3.1. Identification and enrollment

The SWIFT study is a randomized design prospectively enrolling stroke and TIA patients meeting eligibility at Columbia University Medical Center (CUMC). Eligibility for SWIFT includes diagnosis of IS or TIA; over 18 years of age, and living in a household with a telephone. Patients were excluded if unable to give informed consent; discharged to long term nursing home or requiring 24 h care; have a modified Rankin score>4 at baseline; have severe aphasia limiting comprehension; have a pre-stroke dementia history, or have end stage disease resulting in probable mortality $\leq$1 year. Subjects must be able to participate in either an English or Spanish session. After informed consent, a stroke knowledge/behavioral survey is verbally obtained. These surveys have been validated and used in national stroke screening programs [4,5]. The stroke knowledge survey consists of three sections: a multiple choice section focused on stroke warning signs, risk factors, and treatment; hypothetical scenarios with questions focused on action during an acute stroke; and an open ended question to elicit the three most important things to say when speaking to emergency personal about an acute stroke emergency (stroke, symptoms and time/tPA). The adapted stroke survey is scored on a scale from 0 to 100 [6].

Acute stroke times are recorded on all participants. Time parameters collected include onset of stroke symptoms, last known well, time to triage, time to CT scan, and tPA utilization/time. The SWIFT clinical coordinator is responsible for the daily comprehensive screening of the potential stroke/TIA cases from CUMC including the emergency department, and hospital unit — discharged or admitted. This process includes participation in daily stroke rounds and a daily coordinator's meeting. Admission sheets, discharge sheets, and information from the emergency room stroke coordinator are reviewed and eligibility for studies determined. After confirmation of eligibility, coordinators approach the patient at their bedside or in the ED to solicit informed consent. The patient and family are asked to recall the sequence of the current event by using the following protocol of questions:

1. Where were you and what where you doing when the symptoms started?
2. “What time did the symptoms started?”
3. Please, describe the symptoms.
4. Did anyone observe what was happening? (If yes, coordinator is instructed to get contact information to obtain details about the event with emphasis on time onset.)
5. If the patient does not remember exactly when the symptoms started, the coordinator is instructed to ask probing questions including; “When was the last time you remember feeling well (at your baseline)?”
6. If the patient reported waking up with the symptoms, they are asked, “Were you completely well when you went to sleep? What time did you go to sleep?” (As per protocol, this time will be recorded as the last time seen well if the patient woke up with the symptoms and no witnesses recalled the event.)

When the patient is not sure about the exact time, probing questions are asked to estimate time of the symptoms onset. All confirmed times are recorded in the data base.

Prior to randomization, health educators collect baseline data through a structured in-person interview including demographics, psychosocial, socioeconomic factors, medical history, vascular risk factors, family history of stroke and cardiac disease, cognitive battery, and functional assessment. Standardized questions were adapted from the Behavioral Risk Factor Surveillance System [7]. Subjects complete a functional and cognitive status battery [8]. Mutually exclusive insurance categories are defined as no insurance (NINS), private insurance (PVT), Medicare only (MCR), and Medicaid (MCD) $\pm$ Medicare. Social support is defined by marital status, friendship, networks and social activities.

Blood pressure (BP) measurements are taken on all participants using a calibrated standard aneroid sphygmomanometer. After 5 min in a sitting position, two BP measurements are recorded. In subjects with BP recordings discrepant by more than 10 mm Hg, a third measurement is obtained by the study physician.

All assessments are conducted in English or Spanish depending upon the primary language of the subject. Finally,